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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,099	07/11/2001	Geetha Shankar	10602-013-999	1334

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EXAMINER
ULM, JOHN D

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/904,099	Shankar et al.
Examiner	**Art Unit**
John Ulm	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 27, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-18* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *6, 9*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1) Claims 1 to 21 are pending in the instant application. Claims 11 and 12 have been amended as requested by Applicant in Paper Number 11, filed 11 November of 2002.

2) Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

3) Tables 2 to 6 of the instant specification do not comply with 37 C.F.R. 1.52 (b) with respect to spacing and/or font size. 37 C.F.R. 1.52 (b) states that:

" Except for drawings, the application papers (specification, including claims, abstract, oath or declaration, and papers as provided for in this part) and also papers subsequently filed, must have each page plainly written on only one side of a sheet of paper, with the claim or claims commencing on a separate sheet and the abstract commencing on a separate sheet. See §§ 1.72(b) and 1.75(h). The sheets of paper must be the same size and either 21.0 cm. by 29.7 cm. (DIN size A4) or 21.6 cm. by 27.9 cm. (8 ½ by 11 inches). Each sheet must include a top margin of at least 2.0 cm. (3/4 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 2.0 cm. (3/4 inch), and a bottom margin of at least 2.0 cm. (3/4 inch), and no holes should be made in the sheets as submitted. The lines of the specification, and any amendments to the specification, must be 1 ½ or double spaced. The pages of the specification including claims and abstract must be numbered consecutively, starting with 1, the numbers being centrally located above or preferably, below, the text. See § 1.84 for drawings.

37 C.F.R. 1.58 © states that:

Chemical and mathematical formulae and tables must be presented in compliance with § 1.52(a) and (b), except that chemical and mathematical formulae or tables may be placed in a landscape orientation if they cannot be presented satisfactorily in a portrait orientation. Typewritten characters used in such formulae and tables must be chosen from a block (nonscript) type font or lettering style having capital letters which are at least 0.21 cm. (0.08 inch) high (e.g., elite type). A space at least 0.64 cm. (1/4 inch) high should be provided between complex formulae and tables and the text. Tables should have the lines and columns of data closely spaced to conserve space, consistent with a high degree of legibility.

Further, the numbering of the tables is confusing because there is no "Table 1".

Correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4) Claims 1 to 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Ancellin et al. publication (J. BIOL. CHEM. 274(27):18997-19002, 02 Jul. 1999) in view of any two or more of the Conway et al. (J. BIOL. CHEM. 275(27):20602-20609. 07 Jul. 1999), Schöth et al. (MOL. PHARM. 54:154-161, 1998), Wu et al. (J. BIOL. CHEM. 272(14):9037-9042, 04 Apr. 1997), Meng et al. (EUR. J. PHARM. 311:285-292, 1996), Holtmann et al. (J. BIOL. CHEM. 270(24):14394-14398, 16 Jun. 1995), Takagi et al. (J. BIOL. CHEM. 270(17):10072-10078, 28 Apr. 1995), Buggy et al. (J. BIOL. CHEM. 270(13):7474-7478, 1995), Kim et al. (J. BIOL. CHEM. 269(46):28724-28731, 28 Nov. 1994), Gether et al. (J. BIOL. CHEM. 268(11):7893-7898, 15 Apr. 1993) and Kobilka et al. (SCIENCE 240:1310-1316, 03 Jun. 1988, cited by Applicant) publications. The instant claims are drawn to a chimeric Edg receptor, a nucleic acid encoding it and an assay employing it. These claims are specifically encompass a chimeric receptor comprising domain from Edg1 and Edg3.

The Ancellin et al. publication discusses the sphingosine 1-phosphate receptors Edg-1, Edg-2 and Edg-3. This reference specifically disclosed that members of the Edg family of receptors are G protein-coupled receptors and that Edg-3 and Edg-5 "are closer in sequence identity to EDG-1" than any other known Edg receptor. This reference, considered as a whole, taught that Edg-1, Edg-3 and Edg-5 were structurally related G protein-coupled receptors having similar but distinct pharmacological characteristics and that they were involved in the regulation of specific biological processes by coupling to discrete signaling pathways.. This reference did not teach the construction of chimeric Edg receptors.

Each and every one of the Conway et al. (Figure 3), Schöth et al. (Figure 2), Wu et al. (Figure 1), Meng et al. (Tables 1 to 3), Holtmann et al. (Figures 1 and 6), Takagi et al. (Figure 2), Buggy et al. (Figure 2), Kim et al. (Table 1, Figures 2, 5 and 6), Gether et al. (Table 1, Figures 1 and 2) and Kobilka et al. (Figures 1 to 3 and 5 to 8) publications described the construction of a series of chimeric G protein-coupled receptors composed of various combinations of structural domains from two different but related G protein-coupled receptors having distinct pharmacological properties for the purpose of identifying those structural domains in each of those two related receptors that are responsible for the specific pharmacological properties of that receptor. All of these references taught the production of the chimeric receptors described therein by employing recombinant nucleic acids encoding them. Each of these secondary references also described functionality assays employing the chimeric receptors described therein to determine if a functional property associated with one of the parental receptors is retain in a chimeric receptor. A combination of any two or more of these references shows that this technique was a routine practice in the art of studying the molecular biology of G protein-coupled receptors prior to the time that the instant invention was made. Because the Ancellin et al. publication disclosed that Edg-1 and Edg-3 were structurally related but pharmacologically distinct G protein-coupled sphingosine 1-phosphate receptors, an artisan of ordinary skill in the art of G protein-coupled receptor biology would have found it *prima facie* obvious to have constructed a series of chimeric Edg receptors composed of various combinations of transmembrane, intracellular and extracellular domains from Edg-1 and Edg-3 for the purpose of identifying those structural

domains in each of those two related receptors that are responsible for the specific pharmacological properties of that receptor. Because this technique had been successfully applied to a diverse assortment of G protein-coupled receptors prior to the time of the instant invention, as shown by the number of secondary references describing the application of this technique to different pairs of related receptors, an artisan had more than a reasonable expectation that this technique would be applicable to the structure/functional analysis of the Edg-1 and Edg-3 receptors described in the Ancellin et al. publication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800